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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,171	09/09/2003	Roddi James Simpson	0100/0162	1010

21395 7590 07/14/2005

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EXAMINER

HAN, MARK K

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,171

Applicant(s)

SIMPSON ET AL.

Examiner

Mark K. Han

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/9/03; 5/23/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Invention II, Species I in the reply filed on 23 May 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-9 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 May 2005.

Specification

3. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked 35 U.S.C. 112, 6th paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets for the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 11, 1st and 2nd paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)..." (Also see MPEP 2181 [Rev. 1, February 2000])

Appropriate correction is required.

Claim Objections

4. Claims 10-16 and 18-25 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked 35 U.S.C. 112, 6th paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-12, 15, 18-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,643,219 to Burns.

Burns discloses a syringe 37 having a barrel, needle hub 20, collar reception means 28, collar 48, needle protection housing 38, slot 46 having a channel, groove 28, collar having at least one protrusion 54, at least one locking portion 58 and another locking portion 30. See Figures 1-11. In reference to claims 15 and 23, it assumed that the distal end of the syringe and the collar are at least substantially flush, otherwise, the sheath would not be able to hinge to cover the needle as required by the Burns invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns.

In reference to claims 14 and 22, Burns discusses the use of at least one protrusion to engage the collar to the syringe. Burns does not expressly discuss the use of a plurality of flanges. It is considered that a plurality of flanges is a functionally equivalent alternative to the at least one protrusion of Burns that is well-known in the mechanical arts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plurality of flanges for the at least one protrusion of Burns since it was known in the art that a protrusion and a plurality of flanges are interchangeable.

In reference to claim 25 Burns discusses the use of a groove and at least one protrusion as discussed above. It is considered that a boss and a notch is a functionally equivalent alternative to the groove and protrusion of Burns that is well-known in the mechanical arts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a boss and a notch for the groove and protrusion of Burns since it was known in the art that a boss/notch and a groove/protrusion are interchangeable.

7. Claims 13, 16, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns in view of U.S. Patent No. 5,681,295 to Gyure et al. (hereinafter "Gyure").

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Burns discloses the claimed invention as shown above. Burns, however, does not show a catch or a semicircular portion. Gyure, discloses a pivotable sheath having a catch 58 and a semicircular portion 69. See Figures 1-13. It would have been obvious to one of ordinary skill in the art to include a catch and semicircular portion, as suggested by Gyure, in the Burns invention in order to secure the needle to the sheath and to provide a platform for the user to provide sufficient torque to pivot the needle sheath to enclose the needle.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Mark K. Han
Patent Examiner
Art Unit 3763

mkh

July 11, 2005



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